

**REMARKS**

Claims 1-73 are pending, and claims 1-4, 6-14, 22-24, 26-39, and 48-73 are currently under consideration. Applicants' cancel, without prejudice, claims 27 and 67-69. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note that the finality of the previous Office Action has been withdrawn.

2-3. Claims 1-4, 6, 7, 9-14, 22-24, 26, 28-33, 35, 48, 50, 56-62, 67 and 68 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to enable one of skill in the art to practice the claimed invention. Applicants traverse this rejection to the extent it is maintained in light of the amended claims.

The basis of the rejection is two-fold. First, the Examiner alleges that Applicants failed to enable fragments including seven repeats of the hexameric sequence represented in SEQ ID NO: 1. Second, the Examiner alleges that Applicants failed to enable routes of administration other than direct administration to a site in vivo. Regarding both grounds of rejection, Applicants respectfully submit that the Examiner has failed to establish any factual basis for maintaining this rejection. The Examiner has stated the unpredictability in the art, but has failed to address Applicants arguments that the data provided in the specification and by Applicants post-filing resolves these concerns.

Nevertheless, to expedite prosecution, Applicants have amended the claims to more particularly point out certain embodiments of the invention. Specifically, Applicants have amended the claims to more particularly point out (i) the elastin-based compositions within the scope of the claims and (ii) the routes of administration required by the claimed methods of treatment. Applicants' amendments are not in acquiescence to the rejection. Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are respectfully requested.

4-6. Claims 1-4, 6-8, 10, 12, 48, 49, 60, 61, 63, 65, and 69 are rejected under 35 U.S.C. 102(a) as anticipated by Weiss et al. Alternatively, the claims are rejected under 35 U.S.C. 103(a) as

obvious over Weiss et al. Applicants traverse these rejection to the extent they are maintained in light of the amended claims.

In accordance with MPEP 2131 and with the Courts, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicants contend that Weiss et al. fail to satisfy the criteria necessary to anticipate the claimed invention. Nevertheless, to expedite prosecution, Applicants have amended the claims to more particularly point out certain embodiments of the invention. Applicants’ amendments are not in acquiescence to the rejection. Applicants reserve the right to prosecute claims of similar or differing scope. The amended claims are directed to, for example, the subject matter recited in previously pending claims 67 and 68. Applicants note that claims 67 and 68 were not rejected in view of Weiss et al., thereby further supporting the contention that Applicants’ amendments obviate these rejections.

Specifically, Weiss et al. fail to teach or suggest elastin-based compositions consisting of polypeptides consisting of, for example, (i) an amino acid sequence at least 95% identical to SEQ ID NO: 3, (ii) an amino acid sequence represented by SEQ ID NO: 2, or (iii) a peptide fragment of six repeats of the hexameric sequence represented by SEQ ID NO: 1, as recited by the pending claims. Given that Weiss et al. fail to teach or suggest each and every limitation of the claimed invention, Weiss et al. fail to anticipate the claimed invention. Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants’ amendments to the claims additionally obviate the rejection under 35 U.S.C. 103(a). Briefly, as outlined above, Weiss et al. fail to teach or suggest each and every limitation of the claimed invention. Additionally, Weiss et al. fail to suggest any benefits of modifying their teachings to arrive at the presently claimed invention. Absent any such teachings, Weiss et al. is insufficient to establish a *prima facie* case of obviousness. Reconsideration and withdrawal of this rejection is respectfully requested.

7. Claims 1-4, 6-8, 10-12, 48, 49, 60, 61, 63, 65, and 69 are rejected under 35 U.S.C. 102(b) as anticipated by Rothstein et al. Alternatively, the claims are rejected under 35 U.S.C. 103(a) as obvious over Rothstein et al. Applicants traverse this rejection to the extent it is maintained in light of the amended claims.

In accordance with MPEP 2131 and with the Courts, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicants contend that Rothstein et al fail to satisfy the criteria necessary to anticipate the claimed invention. Nevertheless, to expedite prosecution, Applicants have amended the claims to more particularly point out certain embodiments of the invention. Applicants’ amendments are not in acquiescence to the rejection. Applicants reserve the right to prosecute claims of similar or differing scope. The amended claims are directed to, for example, the subject matter recited in previously pending claims 67 and 68. Applicants note that claims 67 and 68 were not rejected in view of Rothstein et al., thereby further supporting the contention that Applicants’ amendments obviate these rejections.

Specifically, Rothstein et al. fail to teach or suggest elastin-based composition consisting of polypeptides consisting of, for example, (i) an amino acid sequence at least 95% identical to SEQ ID NO: 3, (ii) an amino acid sequence represented by SEQ ID NO: 2, or (iii) a peptide fragment of six repeats of the hexameric sequence represented by SEQ ID NO: 1, as recited by the pending claims. Given that Rothstein et al. fail to teach or suggest each and every limitation of the claimed invention, Rothstein et al. fail to anticipate the claimed invention. Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants’ amendments to the claims additionally obviate the rejection under 35 U.S.C. 103(a). Briefly, as outlined above, Rothstein et al. fail to teach or suggest each and every limitation of the claimed invention. Additionally, Rothstein et al. fail to suggest any benefits of

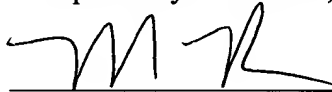
modifying their teachings to arrive at the presently claimed invention. Absent any such teachings, Rothstein et al. is insufficient to establish a *prima facie* case of obviousness. Reconsideration and withdrawal of this rejection is respectfully requested.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945, under Order No. HYDR-P01-002.**

Date: September 16, 2005

Respectfully Submitted,



---

Melissa S. Rones  
Reg. No. 54,408  
Ropes & Gray LLP  
One International Place  
Boston, MA 02110  
Phone: 617-951-7000  
Fax: 617-951-7050